K073663
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**510k Summary**

**GelSpray™ Liquid Bandage 510K Summary**

**Submitter: BioCure, Inc.**
**2975 Gateway Drive**
**Suite 100**
**Norcross, GA 30071**

**Contact: Mr. Sameer Shums**

**Name of device: Liquid Bandage**

**Proprietary/Trade Name: GelSpray™ Liquid bandage**

**Classification name: Liquid bandage**

**510(k) Numbers and Product Codes of equivalent devices.**

3M company
3M Liquid Bandage; Bandage, Liquid
Code: KMF (21CFR 880.5090); K053409; S.E. June 19, 2006

Johnson & Johnson
Johnson & Johnson Liquid bandage; bandage, Liquid
Code: KMF (21CFR880.5090); K062602; S.E. December 11, 2006

**Indications for Use and Intended Population**

GelSpray™ Liquid Bandage is indicated for use to cover minor cuts, scrapes and minor irritations of the skin.

**Device Description**

The GelSpray™ Liquid Bandage is a two part hydrogel system, capable of rapid curing when applied to a wound bed. The GelSpray™ Liquid Bandage consists of a macromer derived from polyvinyl alcohol (PVA). When mixed, the pre-polymers utilize a *redox* reaction to cure, resulting in the final dressing consisting predominantly of water (approximately 80%). The pre-polymer components are initially packaged and sterilized in a two part syringe with a common plunger for delivery. A static mixer is incorporated in the delivery system to ensure a uniform and adequate mix of the two pre-polymers and to allow a controlled delivery of the dressing to its intended site.

The product will be supplied sterile and packaged in a pre-filled, double barrel syringe. The target quantity will be providing the user with 4.5mL minimum.

**Similarities and Differences to Predicates**

The Intended Use of GelSpray™ Liquid Bandage and the predicate devices are the same and unchanged, primarily other than product names.

GelSpray™ Liquid Bandage is supplied in a two barreled syringe, with applicator, and is un-polymerized prior to use. At the time of application, the two components in each barrel of the syringe are mixed and begin to polymerize immediately on application. Both GelSpray™ Liquid bandage and the predicate devices utilize in-situ polymerization. GelSpray™ Liquid bandage has similar properties to the predicate devices, however uses GelSpray™ Liquid Bandage uses PVA and the predicate devices use cyanoacrylates. GelSpray™ Liquid Bandage and the predicate devices have similar biocompatibility profiles.

Biocompatibility testing and design validation testing provided in the 510K have demonstrated that GelSpray™ Liquid bandage has the same performance, safety and technical characteristics such that no new issues of safety or effectiveness are raised.

There are more similarities than differences when comparing BioCure's GelSpray™ Liquid Bandage to the predicate devices.

**Conclusion**

There are more similarities than differences between the predicate devices and BioCure GelSpray™ Liquid Bandage. The predicate devices and GelSpray™ Liquid Bandage have the nearly the same intended use, warnings, precautions and contraindications. When used in accordance with the instructions for use, by qualified personnel, the BioCure GelSpray™ Liquid Bandage is safe and effective, as indicated, for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2008

BioCure, Incorporated
% Generic Devices Consulting, Inc.
Mr. John Greenbaum
President
20310 Southwest 48th Street
Southwest Ranches, Florida 33332

Re: K073663
Trade/Device Name: GelSpray™ Liquid Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: Class I
Product Code: KMF
Dated: December 20, 2007
Received: December 26, 2007

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**



510(k) Number(if known): K073663

Device Name: GelSpray™ Liquid Bandage

Indications For Use:

GelSpray™ Liquid Bandage is indicated for use to cover minor cuts, scrapes and minor irritations of the skin.

Prescription Use_X_ OR Over-The-Counter Use___
(Per 21 CRF 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K073663